



RAVIMIAMET

Juliette Omtzigt  
Reddy Holding GmbH  
Kobelweg 95 Kriegshaber  
86156 Augsburg  
GERMANY

29.04.2024 nr RKU-4/27

## DECISION

to grant authorisation for clinical trial on the basis of Regulation (EU) No 536/2014 of the European Parliament and of the council

State Agency of Medicines has received the application from sponsor Dr Reddy's Laboratories Limited on 28.12.2023 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (1) of Estonian Medicinal Products Act (MPA).

Based on art 8 of Regulation (EU) No 536/2014, considering the aspects covered by Part I and Part II of the assessment report, on the basis of § 99<sup>6</sup> section 1 p 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no AB-01-004 under the following conditions:

**protocol no:** AB-01-004 (Version 2.0-EU-V1.0, dated March 29, 2024)

**full title of the trial:** A randomised, double-blind, multicentre study comparing the efficacy, safety and immunogenicity of proposed Abatacept biosimilar (DRL\_AB) with Orencia® administered by the intravenous route as an add-on to methotrexate in the treatment of patients with moderate to severe rheumatoid arthritis

**sponsor of the trial:** Dr Reddy's Laboratories Limited

**number of subjects in Estonia:** 14

**starting date:** May 2024

**principal investigators and study locations:**

- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Ene Ojassalu, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Raili Müller, MediTrials OÜ, Mõisavahe tn 34c, 50708 Tartu, Estonia

The addressee may file a challenge with State Agency of Medicines within 30 days as of the day when the addressee became or should have become aware of the decision as prescribed in Code of Administrative Procedure § 71(1). If the addressee wishes to have the decision to annulled by the administrative court, he or she may submit a complaint to the Tartu Administrative Court as prescribed in § 7(1) and § 46(1) of the Code of Administrative Court Procedure within 30 days after the date on which the decision was notified to the applicant.

(digitally signed)

Katrin Kiisk  
Director General